

EXHIBIT J

Donald R. Ostergard, M.D.

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

Master File No. 2:12-MD-02327 MDL 2327

DEPOSITION OF
DONALD R. OSTERGARD, M.D.

March 9, 2016

IN RE: ETHICON, INC., PELVIC REPAIR JOSEPH R. GOODWIN
SYSTEM PRODUCTS LIABILITY LITIGATION U.S. DISTRICT JUDGE

THIS DOCUMENT RELATES TO THE FOLLOWING CASES
IN WAVE 1 OF MDL 200:

HARRIET BEACH v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00476
SHARON BOGGS, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00368
ROBIN BRIDGES v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00651
ANGELA COLEMAN, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-01267

AMANDA DELEON, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00358
DENNIS W. DIXON, ESTATE OF VIRGINIA DIXON,
Deceased v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-01081
DINA DESTEFANO-RASTON, ET AL. v. ETHICON, INC.,
ET AL.
Civil Action No. 2:12-cv-01299
PAULA FISK v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00848

JACKIE FRYE v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-1004
TERESA GEORGILAKIS, ET AL. v. ETHICON, ET AL.
Civil Action No. 2:12-cv-00829

ROSE GOMEZ, ET AL. v. ETHICON, ET AL.
Civil Action No. 2:12-cv-00344

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1 LOUISE GRABOWSKI v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00683
2
PAMELA GRAY-WHEELER v. ETHICON, INC., ET AL.
3 Civil Action No. 2:12-cv-00455
4 DAWNA HANKINS v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00369
5
JEANIE HOLMES, ET AL. v. ETHICON, INC., ET AL.
6 Civil Action No. 2:12-cv-01206
7 NANCY HOOPER, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00493
8
WILMA JOHNSON v. ETHICON, INC., ET AL.
9 Civil Action No. 2:12-cv-00809
10 BEVERLY KIVEL v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00591
11
PAUL KRIZ, ET AL. v. ETHICON, INC., ET AL.
12 Civil Action No. 2:12-cv-00938
13 DEBORAH LOZANO, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00347
14
BARBARA MASSICOT v. ETHICON, INC., ET AL.
15 Civil Action No. 2:12-cv-00856
16 EDITH NOLAN v ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00864
17
NOEMI PADILLA v. ETHICON, INC., ET AL.
18 Civil Action No. 2:12-cv-0567
19 STACEY PANGBORN v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-01198
20
MIRANDA PATTERSON v. ETHICON, INC., ET AL.
21 Civil Action No. 2:12-cv-00481
22 JENNIFER REYES, ET AL. v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00939
23
JENNIFER SIKES, ET AL. v. ETHICON, INC., ET AL.
24 Civil Action No. 2:12-cv-00501
25

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1 CARRIE SMITH v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00258

2
JANET SMITH, ET AL. v. ETHICON, INC., ET AL.
3 Civil Action No. 2:12-cv-00861

4 MARGARET STUBBLEFIELD v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00842

5
MARY LEE SWEENEY, ET AL. v. ETHICON, INC., ET AL.
6 Civil Action No. 2:12-cv-00807

7 KRYSTAL TEASLEY v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00500

8
SUSAN THAMAN v. ETHICON, INC., ET AL.
9 Civil Action No. 2:12-cv-00279

10 PATRICIA TYLER v. ETHICON, INC., ET AL.
Civil Action No. 2:12-cv-00469

11
CATHY WARLICK, ET AL. v. ETHICON, INC., ET AL.
12 Civil Action No. 2:12-cv-00276

13
14 The deposition of DONALD R. OSTERGARD, M.D.,
15 taken before Leeann Keenan, a Registered Merit
16 Reporter, Certified Realtime Reporter, and a Notary
17 Public in and for the County of Summit and the State
18 of Colorado, at 7171 West Alaska Drive, Lakewood,
19 Colorado, on Wednesday, March 9, 2016, at the hour
20 of 9:01 a.m., pursuant to Notice.

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1 APPEARANCES:

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1 significant finding.

2 Q. My question is focused on Level 1, so
3 randomized control trials.

4 A. Well, since all mesh degrades, what do
5 you expect?

6 Q. Why is it that you believe that all mesh
7 degrades?

8 A. Every mesh available, every
9 manufacturer's mesh is capable of degradation, but
10 not every patient who has mesh will have
11 degradation, necessarily. But, again, very large
12 numbers of patients have not had explants of their
13 mesh. Now, I know that one pathologist at least has
14 seen degradation in the mesh of all the various
15 manufacturers.

16 Q. If we leave out plaintiffs' expert,
17 Dr. Iakovlev.

18 A. That's correct.

19 Q. Let's put him to the side.

20 A. Excuse me?

21 Q. Let's put him to the side.

22 A. Why? I can't put him to the side. He's
23 confirming --

24 Q. For purposes --

25 A. -- what Ethicon actually found in 1983.

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1 Q. For purposes of my question --

2 A. As --

3 Q. For purposes of my question, I'm not
4 focused on him. I want to go back to my question.

5 So are there any Level 1
6 randomized control trials that report degradation
7 with Gynemesh PS?

8 MS. THOMPSON: Object to form.

9 A. There's no randomized control trials. I
10 mean, no one has ever taken 100 patients with the
11 mesh there, extracted that mesh from those 100
12 patients and looked at it. That would be something
13 no Human Subjects Committee would approve, so it's
14 not possible to do such a study. So to answer your
15 question, there is no Level 1 evidence --

16 Q. Okay.

17 A. -- from such a study designed that way.

18 Q. So the surface cracking that you
19 mentioned, a study has not been done yet which shows
20 whether that is a finding in patients who have good
21 prolapse repair and no complications as compared to
22 patients who have complications, true?

23 A. Well, the mesh is --

24 MS. THOMPSON: Object to form.

25 A. -- available for analysis. It comes from

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1 patients who have a complication severe enough to
2 remove that mesh. It couldn't be done otherwise.
3 No Human Subjects Committee would approve that.

4 Q. What I'm saying is the surface cracking
5 that's been reported by some folks, that could be a
6 normal finding in asymptomatic patients with good
7 cure of their prolapse and no complications because
8 the study -- a study hasn't been done with that type
9 of control to show whether this cracking is actually
10 causal of any of the complications, true?

11 MS. THOMPSON: Object to form.

12 A. At this point in time, we cannot
13 specifically relate degradation to complications in
14 patients. The only time we are able to see this
15 degradation, and I think this was mentioned in one
16 of Ethicon's patients -- oh, it is attached to one
17 of the expert reports, or is mentioned that on
18 removal of the mesh, it fell apart. It fell apart,
19 so all the mesh could not be taken out.

20 And this has been my experience as
21 well. The mesh frequently does that. You can't get
22 it all out. And even Ethicon has likened this to
23 rebar in concrete. You can't get the rebar out.
24 And now these patients have remaining polypropylene
25 mesh in them, which can at some time in the future

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1 cause problems for them.

2 And I hate to bring up the cancer
3 issue, but there are now two neoplasms that have
4 been described with polypropylene mesh. And they'll
5 actually be published formally next month, and so
6 these patients have this knowledge if that work gets
7 caught in the media attention and the media says
8 that it causes cancer. Well, there's no proof it
9 causes cancer. It's just an association at this
10 point. But these patients then are going to be
11 clamoring to have their mesh taken out so they don't
12 have to worry about the possibility of cancer
13 sometime in the future, and I think this is a major
14 issue.

15 Q. So I'm going to respectfully move to
16 strike some of your answer that went beyond my
17 question.

18 MR. SNELL: Can you read back his
19 answer where he says, "At this point we cannot
20 relate degradation to complications." I think
21 something like that.

22 (Record read as follows:
23 at this point in time, we cannot
24 specifically relate degradation
25 to complications in patients.

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1 comparisons.

2 Q. Is it correct then that you do not hold
3 an opinion as to the adequacy of the Prolift IFU?

4 MS. THOMPSON: Object to form.

5 A. That is not correct.

6 Q. Are you basing -- well, do you -- do you
7 have an opinion then that the Prolift IFU is
8 inadequate in some form or fashion?

9 A. Yes. It doesn't warn against
10 degradation, for one thing.

11 Q. So is there any regulatory standard that
12 you have considered and factored in in that opinion?

13 A. A regulatory standard for devising an
14 IFU?

15 Q. Yes.

16 A. I'm not sure if one exists.

17 Q. Is it your opinion that the IFU should --
18 strike that.

19 Is it your opinion that the
20 Prolift IFU should say that the mesh can degrade?

21 A. Yes, absolutely.

22 Q. And that is based on your personal
23 opinion, true?

24 MS. THOMPSON: Object to form.

25 A. That is based on my opinion and my review

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1 of the information regarding degradation, when
2 Ethicon knew about it and physicians should have
3 been told. It's a very important factor in their
4 decision whether or not to use a product.

5 Q. Have you done any study of physicians'
6 attitudes as to whether surface degradation would
7 lead them to not use Prolift?

8 MS. THOMPSON: Object to form.

9 A. I have not done any such studies.

10 Q. Hypothetically, if degradation were to
11 occur, the clinical manifestation of that, if any,
12 would be variable, true?

13 MS. THOMPSON: Object to form.

14 A. Well, since we don't know what the
15 manifestations are, it's very difficult to answer
16 that question.

17 Q. Fair enough.

18 When did you first look at the
19 Prolift IFU?

20 A. When did I first look at it?

21 Q. Yes.

22 A. I can't tell you the exact date.

23 Q. Okay. You have looked at it, though?

24 A. I have looked at it, yes.

25 Q. Okay.

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1 MR. SNELL: Let's mark it.

2 (Exhibit No. 16 was marked.)

3 Q. 16.

4 A. Thank you.

5 MS. THOMPSON: Thank you.

6 Q. We've talked about a whole lot of
7 different complications that can occur with the
8 different prolapse surgeries.

9 Mesh exposure/erosion, that's a
10 unique risk with mesh, correct?

11 A. Quite unique.

12 Q. Conversely, you can have suture erosions
13 with non-mesh repair, true?

14 A. Which are typically of no consequence,
15 whereas the erosions that you're speaking of do have
16 consequences.

17 Q. There can be contraction with Prolift,
18 correct?

19 A. Yes.

20 Q. And there's also tissue contraction with
21 native tissue, true?

22 MS. THOMPSON: Object to form.

23 A. Depends on how the surgery is done. It
24 can be avoided, generally.

25 Q. Well, if there's scarring, there's going

REPORTER'S CERTIFICATE

I, LEEANN L. KEENAN, Registered Merit Reporter and Certified Realtime Reporter within Colorado, appointed to take the deposition of DONALD R. OSTERGARD, M.D., do hereby certify that before the deposition he was duly sworn by me to testify to the truth; that the deposition was taken by me at 1801 California Street, Suite 5100, Denver, Colorado; then reduced to typewritten form herein; that the foregoing is a true transcript of the questions asked, testimony given and proceedings had.

I further certify that I am not related to any party herein or their Counsel, and have no interest in the result of this litigation.

In witness hereof I have hereunto set my hand this 28th day of March, 2016.



Leeann L. Keenan
Registered Merit
Certified Realtime Reporter
and Notary Public



My commission expires June 8, 2016